

Divisional of U.S.S.N. 09/433,486
"Porous Drug Matrices and Methods for Manufacture Thereof"
By: Julie Straub, Howard Bernstein, Donald E. Chickering, III,
Sarwat Khattak, and Greg Randall
Express Mail Label No.: EL 690 662 580 US
Date of Deposit: November 3, 2000
PRELIMINARY AMENDMENT

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cont
Q4
Cont.

--35. The method of claim 23 wherein the mean diameter of the microparticles is between about 0.5 and 5 μm .--

Remarks

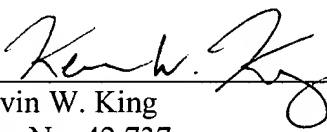
Claims 1-22, which were the subject of a restriction requirement in the parent application, have been canceled. Claims 23, 25, and 32 have been amended to clarify the claimed invention, and to correct spelling and antecedent basis of the claims. New claims 33-35 have been added. Support for new claims 33 and 34 is found, for example, in claim 1 as originally filed, and support for new claim 35 is found, for example, at page 5, lines 28-30. No new matter has been added. A copy of the claims as amended is provided in the attached Appendix for the convenience of the Examiner.

The invention defined by the claims utilizes a porous matrix having drug particles dispersed therein. The matrix is a porous matrix wherein the porosity is defined by the TAP density of the material ($\leq 1.0 \text{ g/mL}$) and having a surface area $\geq 0.2 \text{ m}^2/\text{g}$. The drug particles are defined as having a diameter between 0.1 and 5 μm and a total surface area greater than 0.5 m^2/mL .

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Examination and allowance of claims 23-35 is respectfully requested.

Respectfully submitted,



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Date: November 3, 2000

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APPENDIX

Claims as Preliminarily Amended

1-22. (Canceled).

23. (Once amended) A method of delivering a drug to a patient in need thereof, comprising

administering a therapeutically or prophylactically effective amount of the drug in a formulation comprising a porous matrix [formed of] which comprises a wetting agent and microparticles of the drug, wherein the microparticles have a mean diameter between about 0.1 and 5 μm and a total surface area greater than about 0.5 m^2/mL , and wherein the [dry] porous matrix [is in a dry powder form having] has a TAP density less than or equal to 1.0 g/mL and/or [having] has a total surface area of greater than or equal to 0.2 m^2/g and is in the form of a dry powder.

24. The method of claim 23 wherein the formulation is suitable for administration by a route selected from the group consisting of parenteral, mucosal, oral, and topical administration.

25. (Once amended) The method of claim 24 wherein the parenteral route is selected from the group consisting of [intravenous,] intravenous, intraarterial, intracardiac, intrathecal, intraosseous, intraarticular, intrasynovial, intracutaneous, subcutaneous, and intramuscular administration.

26. The method of claim 24 wherein the mucosal route is selected from the group consisting of pulmonary, buccal, sublingual, intranasal, rectal, and vaginal administration.

27. The method of claim 23 wherein the formulation is suitable for intraocular or conjunctival administration.

28. The method of claim 23 wherein the formulation is suitable for intracranial, intralesional, or intratumoral administration.

29. The method of claim 23 wherein the formulation is in an aqueous solution suitable for parenteral administration.

30. The method of claim 23 wherein the formulation is in a tablet or capsule suitable for oral administration.

31. The method of claim 23 wherein the formulation is in a suppository suitable for vaginal or rectal administration.

32. (Once amended) The method of claim 23 wherein the formulation is [a dry powder] suitable for pulmonary administration.

33. (New) The method of claim 23 wherein the dry powder form of the porous matrix has a TAP density less than or equal to 1.0 g/mL.

34. (New) The method of claim 23 wherein the dry powder form of the porous matrix has a total surface area of greater than or equal to 0.2 m²/g.

35. (New) The method of claim 23 wherein the mean diameter of the microparticles is between about 0.5 and 5 μm.